K040114

JAN 2 9 2004

Special 510(K) Summary

1. Name of Submitter:

Abbott Laboratories
Hospital Products Division
200 Abbott Park Road
Abbott Park, Illinois 60064-6133

Establishment Registration # 1415939

2. Manufacturer and Establishment Registration Number:

Abbott Laboratories
Hospital Products Division
755 Jarvis Drive
Morgan Hill, CA 95037

Establishment Registration # 2921482

3. Proprietary or Trade Name: Abbott DataPort PC™

4. Common Name: Infusion Pump

5. Device Classification, Pancode and ProCode: Class II, 80, FRN

6. Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for intravenous infusion pumps. Infusion pumps are listed in 21 CFR 880.5725.

7. Intended Use:
The Abbott DataPort PC is an optional computer (PC) software accessory for use exclusively with the Abbott Plum A+ and A+3 Infusion Pumps in a biomedical technical service environment.

8. Indications for Use:
The indications for use are the same as the indications for use of the parent devices belonging to the Abbott Plum A+ Infusion Pump family, which are the Abbott Plum A+ and Abbott Plum A+3 Infusion Pumps. Infusion pumps in the Abbott Plum A+ Infusion Pump Family are used in parenteral, enteral and epidural therapies and the administration of whole blood and blood products. The Abbott Plum A+ and A+3 Infusion Pumps are designed to deliver infusions over a broad range of infusion rates from multiple container types.

9. Device Description:

The Abbott DataPort PC software supports data transfer between a single computer (PC) and up to 15 Abbott Plum A+ Infusion Pumps, or up to 4 Abbott Plum A+3 Infusion Pumps. Abbott DataPort PC allows authorized users to retrieve infuser alarm logs, event history logs, and biomedical settings from interfaced infusers, and to edit and send modified biomedical settings to the interfaced infusers from the PC.

10. Statement of Substantial Equivalence:

Infusion pumps in the Abbott Plum A+ Infusion Pump Family using the optional Abbott DataPort PC software for data transfer are substantially equivalent to infusion pumps in the Abbott Plum A+ Infusion Pump Family using software programmed by the facility, or a facility contracted software developer, for data transfer.

The Abbott Plum A+ and Abbott Plum A+3 infusers with optional Abbott DataPort PC software are substantially equivalent to currently marketed Abbott Plum A+ and Abbott Plum A+3 infusers using interface software not supplied by Abbott in that:

Similarities:

1) Both configurations have the same intended use and indications for use.
2) Both configurations use the same fundamental scientific technology.
3) Both configurations have the same physical, operational, and performance specifications.
4) Both configurations allow for data transfer via the infuser data communication ports.
5) Both configurations use the same communication protocol for data transfer.
6) Both configurations use the same accessory hardware for interfacing a PC to the infusers.
7) Both configurations allow for data transfer from a standalone PC to up to 15 Abbott Plum A+ Infusion Pumps or up to 4 Abbott Plum A+3 Infusion Pumps.
8) Both configurations are intended for use in a biomedical technician environment.
9) Both configurations allow for authorized users to retrieve, save, and print alarm and event history logs from connected infusers.
10) Both configurations do not allow users to program a new therapy into an infuser.
11) Both configurations do not allow users to enter infuser keystrokes remotely.
12) Both configurations do not allow users to monitor infusers that are actively infusing, priming, or being programmed for infusion.
13) Both configurations do not support Hospital Information System / Network interfaces.

Differences:

1) The retrieval, saving, and printing of BioMed configuration settings is possible through the infuser communication dataport with a PC that has the Abbott DataPort PC software installed. BioMed configuration settings cannot be accessed through the infuser communication dataport with a PC using interface software not supplied by Abbott.
2) The editing, saving, and sending of modified BioMed configuration settings is possible through the infuser communication dataport using a PC that has the accessory software installed. BioMed configuration settings cannot be accessed through the infuser communication dataport with a PC using interface software not supplied by Abbott.

11. Predicate Device Information:

Information for Abbott Plum A+/A+3 Infusion Pumps previously cleared for commercial distribution and determined to be appropriate for use as predicates is provided below.

510(k) #	Product Name	Clearance Date
K024084	Abbott Plum A+ Infusion Pump	12/31/02
K021350	Abbott Plum A+3 Multichannel Infusion Pump	05/14/02
K011442	Abbott Plum A+ Infusion Pump	06/05/01
K982159	Abbott Plum A+ Infusion Pump	01/12/99

12. Comparison to Legally Marketed Device(s)

Factors	**Subject Device(s)** Abbott Plum A+/A+3 Infusion Pumps (V11.x) with Abbott DataPort PC	**Predicate Device(s)** Abbott Plum A+/A+3 Infusion Pumps (V11.x)
Intended Use	Intended for use at the direction of or under the supervision of licensed physicians or certified healthcare professionals for intravenous infusion therapy.	Same
Indications for Use	For use in parenteral, enteral and epidural therapies and the administration of whole blood and blood products.	Same
Operating Principle	Infusion of intravenous medications to a patient's vascular system using a stepper motor in conjunction with an in-line cassette to meter IV fluids through dedicated IV administration sets.	Same
Administration Sets and Fluid Contact Materials	Sterile, dedicated, non-pyrogenic administration sets. "Plum" sets.	Same
Physical Features	Size, Weight, Input Lines, Output Lines, Power Sources, Battery Type, Power Cord, Materials	Same
Environmental Features	Operating Temperature, Relative Humidity, Pressure, Storage Temperature	Same
Performance Features	Delivery Rates, VTBI Range, Dose Units, Delivery Accuracy, Delivery Modes, Distal Occlusion Pressure Setting, Default Drug Library	Same
BioMed Configuration Settings	Date and Time, Continue Rate, Deliver Together Mode (Concurrent or Piggyback), Enable Delay Start, Callback Default (Yes/No), Default Distal Occlusion Pressure, Max Rate Cap, Default Units/Drug (as listed in Default Drug Library), Default Dose and Conc Units for Drug	Same
Communication Ports	(1) Serial communication dataport for standalone PC interface with up to (15) Abbott Plum A+ Infusion Pumps or up to (4) Abbott Plum A+3 Infusion Pumps.	Same
Computer Interface Software	Abbott supplied (optional).	Facility software per the Abbott Plum A+/A+3 Programmers Guide.
Computer (PC) Interface Software Features	• Retrieve, save and print alarm and event history logs from connected infusers. • Retrieve, save, and print BioMed Settings from connected infusers. • Edit, save and send modified BioMed Settings to connected infusers.	Retrieve, save and print alarm and event history logs from connected infusers.
Other Features	BarCode Wand (optional)	Same

13. Summary of Substantial Equivalence

The Abbott Plum A+ Family of Infusion Pumps with the optional Abbott DataPort PC software as described in this submission are substantially equivalent to the predicate Abbott Plum A+ Family of Infusion Pumps in that all the infuser configurations have:

1) the same intended use,
2) the same indication for use,
3) the same fundamental technology and operating principle,
4) the same physical, environmental and performance features
5) the same or similar materials of construction for all infuser components,
6) the same dataport communication capabilities

14. Statement of Safety and Effectiveness

The Abbott Plum A+ Family of Infusion Pumps (V11.x) with Abbott DataPort PC software, meets the functional claims and intended use as described in the product labeling, and is as safe and effective as, the Abbott Plum A+ Family of Infusion Pumps without the Abbott DataPort PC software.

Prepared and submitted on January 19, 2004 by:

Patricia Melerski
Manager Regulatory Affairs Device Registration
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 9 2004

Abbott Laboratories
Ms. Patricia Melerski
Manager Regulatory Affairs Device Registration
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Department 0389 Building J45-2N
200 Abbott Park Road
Abbott Park, Illinois 60064-6133

Re: K040114
Trade/Device Name: Abbott Plum A+® Infusion Pump with Abbott DataPort PC™
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: January 19, 2004
Received: January 20, 2004

Dear Ms. Melerski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K040114

Device Name: Abbott Plum A+® Infusion Pump with Abbott DataPort PC™

Indications

The Abbott Plum A+® Infusion Pump with Abbott DataPort PC™ has the following indications for use:

The device is used in parenteral, enteral and epidural therapies and the administration of whole blood and blood products.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (per 21 CFR 801.109) **OR** **Over-The_Counter Use**_____

Nicole Hibbard, Interim Branch Chief
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040114